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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	**PAPER NUMBER**
1617	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,367	RAMPOLDI ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/27/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-18* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Applicants' response of October 27, 2010, to the non-final action dated July 27, 2010, has been entered. No claims were amended, cancelled or newly added. Accordingly, claims 1-18 remain pending in the application and are currently under examination.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, 8, 12, 13, 15, 17 and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bruna et al. (US 6,488,964; effective date December 3, 2002). The rejection set forth on pp. 2-3 of the previous Office action dated July 27, 2010 is maintained for reasons of record and is reiterated as follows:

Bruna et al. discloses a tablet comprising 43% gabapentin and 1.7% PEG 6000 (Example 2). This reads on a gabapentin granulate comprising polyethylene glycol having a melting point of 50-80 degrees Celsius.

Response to Arguments

Applicant's arguments filed 10/27/2010 have been fully considered but they are not persuasive. First, Applicant argues that Bruna discloses preparing the composition

by aggregation with a different process while the present claim is prepared by melt granulation. The Examiner is not persuaded by this argument. MPEP 2113 states, “even though product-by-process claims are limited by and defined by the process determination of patentability is based on the product itself." Therefore, the product does not depend on its method of production and burden shift to applicant to demonstrate evidence to show an unexpected result. Hence, it is the Examiners position that the claimed product is the same as the product disclosed in Bruna, absent evidence to the contrary.

Next, Applicant state that the gabapentin granulate has a melting point of between 50-80 degrees Celsius. The Examiner is not persuaded by this viewpoint. In the response filed 3/25/2010, page 8, paragraph 3, Applicant admitted that PEG alone has a melting point between 50-80 degrees Celsius and is a component incorporated in the gabapentin granulate. Therefore, the gabapentin granulate comprising the PEG is not restricted to having a melting point of 50-80 degrees Celsius.

Claims 1, 5, 7, 8, 9, 12, 13, 15, 17 and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Berner et al. (WO 03/035040; effective date May 1, 2003). The rejection set forth on pp. 3 of the previous Office action dated July 27, 2010 is maintained for reasons of record and is reiterated as follows:

Berner et al. discloses tablets comprising 60% gabapentin and 0-39% PolyOx Coagulant, NF (Example 1). Tablets comprising 50% gabapentin and 24.5% PolyOx Coagulant, NF are also exemplified (Example 2). Berner et al. also disclose tablets

comprising 44.76% gabapentin and 21.99% PolyOx WSR Coagulate, NF and tablets comprising 61.11% gabapentin, 27.09% PolyOx WSR 303, NF and 11.8% additives (Example 3). It should be noted that Polyox WSR is equivalent to PEG and therefore reads on a gabapentin granulate comprising polyethylene glycol having a melting point of 50-80 degrees Celsius.

Response to Arguments

Applicant's arguments filed 10/27/2010 have been fully considered but they are not persuasive. First, Applicant argues that Berner discloses gabapentin formulas manufactured by standard granulation techniques, whereas melt granulation is not standard and is a process which is not carried out in water. The Examiner is not persuaded by this argument because there is no teaching away from the use of melt granulation, which was known at the time of invention. Furthermore, Berner nowhere states that standard granulation techniques are restricted to wet granulation.

Next, Applicant references that a difference is observed in the declaration filed 8/24/2009 which shows obtaining the product from melt granulation is different from the product in melt granulation. The Examiner is not persuaded by this argument because the showing is not in the form of a side-by-side comparison with the granulate product of Berner.

Applicant further argues that in view of *In re Thorpe*, the products in the product-by-process claim must be identical or an obvious variant and the method cannot be disregarded if the method provides a distinct structure or product. Applicant argues that the product-by-process claim limitation results in product that has more stability since

the process is carried out in the absence of granulating liquids and the product possesses different physical properties. The Examiner is not persuaded by this argument, because Applicant has failed to show that by following the procedure in Berner a distinct product is derived than the one instantly claimed by melt granulation.

Applicant further argues the invention is characterized in that PEG is the only granulating agent for the claims method of granulation and the present invention overcomes said drawbacks by non-standard melt granulation. The Examiner is not persuaded by this argument because the claims are not to a method of granulating, but rather a product that is a gabapentin granulate. The claims re product-by-process claims, and regardless of whether the granulate is derived by wet granulation or melt granulation, it is the Examiners position that the product taught by the reference is the same as that being claimed.

Finally, Applicant argues that granulates obtained by melt granulation keeps its original crystalline form, lacks degradation products, have optimum sliding and optimum compressibility. The Examiner is not persuaded by this argument because Applicant has failed to show a side-by-side comparison to show an improved result over that taught by the prior art.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 3, 6, 10, 11, 12, 14 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Berner et al. (WO 03/035040; effective date May 1, 2003) as applied to claims 1, 5, 7, 8, 9, 12, 13, 15, 17 and 18 above. The rejection set forth on pp. 3-6 of the previous Office action dated July 27, 2010 is maintained for reasons of record and is reiterated as follows.

Applicant's Invention

Applicant claims a gabapentin granulate comprising gabapentin and polyethylene glycol having a melting point between 50-80 degrees Celsius.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Berner et al. discloses tablets comprising 60% gabapentin and 0-39% PolyOx Coagulant, NF (Example 1). Tablets comprising 50% gabapentin and 24.5% PolyOx Coagulant, NF are also exemplified (Example 2). Berner et al. also disclose tablets

comprising 44.76% gabapentin and 21.99% PolyOx WSR Coagulate, NF and tablets comprising 61.11% gabapentin, 27.09% PolyOx WSR 303, NF and 11.8% additives (Example 3). This reads on a gabapentin granulate comprising polyethylene glycol having a melting point of 50-80 degrees Celsius. Berner et al. teach that in order to provide for sustained delivery it is preferable that at least 40wt% of gabapentin is retained in the dosage form after 1 hour, however, it may be desired to utilize a dosage form that provides for substantially all of the gabapentin to be delivered over the intended duration, where substantially all is taken to mean at least about 85% (page 8, lines 18-25; limitation of claims). The dosage forms may be formulated as solids or capsules wherein the amount of active agent is 0.1-95% (page 10, lines 17-23; limitation of claims 6, 10, 11 and 16). Hard or soft gelatin capsules which contain the granulates may be used which allows for the granulate to be formulated for controlled release in a gastric retained dosage form (page 11, lines 5-8; page 10, lines 12-19; limitation of claims 6, 10, 11 and 16).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Berner et al. do not exemplify gelatin capsules, however, placing the granulates into gelatin capsules is taught (page 11, lines 5-8; page 10, lines 12-19). Berner et al. fail to exemplify compositions with higher than 80 or 90% by weight of granulate, however, formulating solids or capsules with 0.1-95% of gabapentin is taught (page 10, lines 17-23; limitation of claim 3). Berner et al. do not provide any examples where the composition comprises 70-98% gabapentin, 2-25% polyethylene glycol and 0-20%

additives. However, Example 3 comprises 61.11% gabapentin, 27.09% PolyOx WSR 303 (polyethylene glycol), NF and 11.8% additives, and adjusting the amount of gabapentin to 70-95% would have been within the skill of one ordinary in the art because Berner et al. teach that it may be desired to utilize a dosage form that provides for substantially all of the gabapentin to be delivered. Substantially all is taken to mean at least about 85%.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention utilize the teachings of Berner et al. to further include formulating capsules and a composition comprising 70-98% gabapentin, 2-25% polyethylene glycol and 0-20% additives with a reasonable expectation of success. First, one would have been motivated to formulate the granulates into capsules because Berner et al. teach that capsules allow for the granulate to be formulated for controlled release in a gastric retained dosage form which would protect the drug from gastric juices.

Furthermore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention utilize the teachings of Berner et al. manipulate ranges during routine experimentation to formulate compositions comprising 70-98% gabapentin, 2-25% polyethylene glycol and 0-20% additives with a reasonable expectation of success. Berner teaches that the concentration of gabapentin can range

from 0.1-95% of the formulation and it may be desired to utilize a dosage form that provides for substantially all of the gabapentin to be delivered.

Response to Arguments

Applicant's arguments filed 10/27/2010 have been fully considered but they are not persuasive.

Applicant's arguments are addressed in the above response to argument against Berner.

Claim Objection - Allowable Subject Matter

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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